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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LINDA A. YOUNG and TERRY RUSSELL

Appeal 2009-006346
Application 10/070,799
Technology Center 1600

Decided: December 14, 2009

Before TONI R. SCHEINER, DEMETRA J. MILLS, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the Examiner's rejection of claims 1, 4, 6, 8, 10, 12, 13, 15-17, 19-24, and 30-33. Jurisdiction for this appeal is under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The claims relate to methods of improving or maintaining the condition of the skin and coat of a pet, especially cat and dog pets. To achieve this result, the pets are fed a nutritional agent “which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.” The agent comprises a prebiotic, a probiotic, and a long chain fatty acid.

Claims 1, 4, 6, 8, 10, 12, 13, 15-17, 19-24, and 30-33, which are all the pending claims, stand rejected by the Examiner as follows:

Claims 1, 4, 6, 8, 10, 12, 13, 15-17, 19-24, and 30-33 under 35 U.S.C. § 103(a) as obvious over Shields, Jr. et al. (US 6,156,355, issued Dec. 5, 2000) in view of Cavadini et al (EP 0 862 863 A2, published Sept. 9, 1998) or Marsh et al. (WO 98/56263, published Dec. 17, 1998) (Ans. 3).

Claims 1, 4, 6, 8, 10, 12, 13, 15-17, 19-24, and 30-33 under 35 U.S.C. § 103(a) as obvious over Lowe (Canine Nutrition – Recent Advances, in Biotechnology in the Feed Industry pp. 275-87 (1988)) in view of Marsh, Shields, Cavadini, LabDiet '98 (Product Reference Manual, (1998)), and Matsuura et al. (US 5,756,088, issued May 26, 1998) (Ans. 5).

Claim 1 is representative and reads as follows:

1. A method of maintaining or enhancing the healthy functioning of the skin and coat system of a pet in need of same comprising the step of feeding the pet a food composition comprising a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet, wherein the nutritional agent comprises a prebiotic that comprises about 0.1% to about 20% by weight of the food composition, a probiotic microorganism that comprises about 0.5% to about 20% by weight of the food composition, and a long-chain fatty acid.

STATEMENT OF THE ISSUES

With respect to the first obviousness rejection, the Examiner found that Shields described a pet diet with a prebiotic, a probiotic, and a long-chain fatty acid as recited in claim 1. The Examiner found that Shields did not describe the amount of probiotic as required by claim 1, but found this probiotic amount would have been obvious to persons of ordinary skill in the art based on Cavadini's teaching of a probiotic in pet foods in overlapping amounts (Ans. 4).

With respect to the second obviousness rejection, the Examiner found that Lowe taught a pet diet with probiotics to avoid allergy and associated skin and intestinal problems (Ans. 5). The Examiner found that Marsh taught a pet food with long-chain fatty acids to improve skin and coat, and that Shields, Cavadini, and Matsuura taught pet foods with pre- and probiotics (*id.* at 5-6). The Examiner concluded that the claimed combination would have been obvious to persons of ordinary skill in the art to improve hair and coat as all the claimed components had been shown to be effective for such a purpose (*id.* at 6).

Appellants contend that Shields does not "disclose or suggest" a prebiotic that comprises "0.1 to about 20% by weight" of a food composition as required by claim 1 (App. Br. 12). Appellants contend that Cavadini and Marsh "fail to remedy the deficiencies of Shields." (*Id.*)

Appellants also contend that they have "surprisingly found" that a nutritional agent with "bifido- and lactic-bacteria" maintains "the condition of the skin and coat system of the pet" and that its combination with a prebiotic and "linolenic-acid rich oil" has "unexpected benefits that suggest

a synergistic effect.” (*Id.* at 13.) They contend that Shields only describes fatty acids for this purpose, but not pre- and probiotics, and that none of the cited references recognized this effect (Reply Br. 2-3).

Therefore, the issues are as follows:

Did Appellants establish that the Examiner erred in finding that Shields discloses a prebiotic concentration that meets the limitations of claim 1?

Did Appellants rebut the Examiner’s *prima facie* case with evidence of unexpected results?

Is it necessary for the prior art to have recognized the benefit of prebiotics and probiotics on the skin and coat for it to have met all the limitations of claim 1?

PRINCIPLES OF LAW

Once *prima facie* obviousness has been established, an applicant for a patent can rebut it with

a showing of “unexpected results,” *i.e.*, to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected. The basic principle behind this rule is straightforward – that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious.

In re Soni, 54 F.3d 746, 750 (Fed. Cir. 1995).

“[W]hen an applicant demonstrates *substantially* improved results, as Soni did here, and *states* that the results were *unexpected*, this should suffice to establish unexpected results *in the absence* of evidence to the contrary.”

Id. at 751.

The showing of unexpected results must be factual; argument or conclusory statements do not suffice. *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997).

Unexpected results must also be “commensurate in scope with the degree of protection sought by the claimed subject matter.” *In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005).

It is well-established that an old process is not made patentable by merely recognizing something that was not known before. See *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1373 (Fed. Cir. 2007); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1351 (Fed. Cir. 2002); *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990).

FINDINGS OF FACT (FF)

Shields

1. Shields describes breed-specific dog foods with chicken meat, rice as the predominant grain source, “fruit and/or vegetable as the primary or sole fiber source,” a fat blend, antioxidants, vitamins, herbs, and other components (abstract).
2. The fat blend includes canola oil, salmon oil, and evening primrose oil. The canola and salmon oils serve “as sources of short and long-chain omega-3 fatty acids, while evening primrose oil provides an omega-6 fatty acid called gamma linolenic acid (GLA).” (Col. 6, ll. 12-20.)

3. The blend of canola, salmon, and evening primrose oils provides “full spectrum of polyunsaturated fatty acids including Omega 6 and Omega 3 for maintaining healthy skin and hair coat.” (Col. 15, ll. 26-35.)
4. The foods also comprise “chicory root extract . . . as a source of soluble fiber. This material, a source of inulin, has been reported . . . to promote the growth of beneficial bacteria.” (Col. 6, ll. 45-49.) The fiber is “[g]enerally” present in a range from 0.5 to 10% (col. 6, ll. 49-51).
5. “Chicory extract contains inulin, the parent compound of fructooligosaccharides (FOS) found in IVD Select Care formulas and more recently in EukanuBA diets. This compound is termed a ‘prebiotic’ in that it can be utilized by beneficial microorganisms” (col. 11, ll. 40-44).
- 6.

While these ingredient adjustments provide excellent protection of gastrointestinal function, the Herding diet adds . . . microbial cultures (probiotics or DFM) which provide beneficial organisms to the pet. . . . In this particular formula a combination of *Lactobacillus acidophilus*, *Bacillus subtilis* and *Enterococcus faecium* is used . . . Microbial cultures serve as a source of enzymes to help digest food, competitively exclude harmful bacteria, and synthesize various B vitamins and antimicrobial compounds.

(Col. 11, l. 59 to col. 12, l. 4.)

7. “The combination of prebiotics and probiotics in the same product as a 1-2 punch has been termed ‘synbiotics’ and is the most current trend in progressive yogurt cultures.” (Col. 12, ll. 4-7.)

Cavadini

8. Cavadini describes a pet food product which contains probiotic microorganisms (p. 2, ll. 5-6).

9. The product may contain about 10^4 to about 10^{10} bacterial cells or “about 0.5% to about 20% by weight of the mixture of the probiotic micro-organism and carrier substrate” (p. 5, ll. 22-26).
10. Soluble fiber may also be included, “for example, chicory fibres, inulin, fluc tooligosaccharides, soy oligosaccharides . . . and the like. Preferably the soluble fibre selected is a substrate for the micro-organism selected . . . for promoting beneficial effects. The maximum level of soluble fibre is preferably about 20% by weight . . . chicory may be included to comprise about 1% to about 20% by weight” (p. 3, l. 58 to p. 4, l. 5).

Marsh

11. Marsh describes a food for animals (abstract).
12. The food comprises zinc and linoleic acid to produce a superior skin and coat condition (p. 2, ll. 1-15).
13. Linoleic acid “is an essential nutrient for maintenance of the skin’s barrier function and the precursor of arachidonic acid, which regulates the turnover of skin cells” (p. 2, ll. 17-19). Linoleic acid “is thought to be associated with the physical gloss of the hair” (p. 2, ll. 23-24).

Lowe

14. Lowe teaches the benefits of probiotic microorganisms in a pet diet (p. 280).
15. Lowe states that food allergies in dogs can “manifest itself on the skin” (p. 280). Lowe teaches that probiotics may be beneficial for problems associated with “dietary hypersensitivity” (allergy) and help the immune response (*id.*).

Matsuura

16. Matsuura describes a diet composition having prophylactic and therapeutic effects against dermatosis of pet animals (col. 1, 9-11).
17. The composition comprises fatty acids such omega-3 and omega-6 type fatty acids, preferably, gamma-linoleic acid, alpha-linolenic acid, eicosapentaenoic acid, etc. (col. 2, ll. 3-11).
18. The diet also comprises an anti-flatulent agent, such as a lactic acid bacteria and *Bifidobacterium* (col. 2, ll. 35-42).
19. The concentration of the bacteria is about 10^6 - 10^{10} bacterial cells/per gram diet or 0.00001 to 10 wt % (col. 2, ll. 60-63).
20. The diet can also include fructooligosaccharides to enhance the effect of the anti-flatulent (col. 2, ll. 66 to col. 3, l. 3).
21. Matsuura teaches that the skin condition was improved by the diet (col. 6, ll. 31-35; col. 8, ll. 45-63).

LabDiet

22. LabDiet discloses a standard canine diet that includes linolenic acid and other fatty acids.

Specification

23. The Specification defines a “prebiotic” as a “substance or compound which is fermented by the intestinal flora of the pet and hence promotes the growth and development of bifido- and lactic-bacteria” in the gastrointestinal tract (Spec. 2: 27-30). The Specification teaches that the prebiotics may be provided in the form of plant material and states that extracts of chicory are suitable (Spec. 3: 17-21; 5: 22-23).

ANALYSIS

Prebiotic concentration

Claim 1 recites “a prebiotic that comprises about 0.1% to about 20% by weight of the food composition.” Shields describes chicory root extract, a prebiotic, in an amount from 0.5% to 10% (FF4-5) which is within the claimed broader range. Because the ranges are overlapping, there is a presumption of obviousness. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003). Therefore, the Examiner did not err in finding that Shields met the claimed prebiotic limitation.

Furthermore, Cavadini also teaches the prebiotic chicory in an amount which overlaps with the claimed amounts (FF10). Thus, the claimed amounts would have been presumed obvious based on Cavadini’s disclosure, as well.

Appellants contend that the “crude fiber” described in Shields “is not necessarily equivalent to ‘inulin’ since there are many different kinds of fiber” (Reply Br. 4).

This argument is not persuasive. Claim 1 is not limited to “inulin.” The claim is directed to a “prebiotic.” The Specification defines a prebiotic as a substance that is fermented by bacteria and specifically identifies chicory – the same product in Shields – as suitable (FF23). Therefore, the evidence as a whole supports the Examiner’s position.

Unexpected results

It is well-established that obviousness can be rebutted by a showing of unexpected results as compared to the prior art. Appellants contend that a

nutritional agent comprising “bifido- and lactic-bacteria” produce surprising results, as does the combination of prebiotics with linoleic acid (App. Br. 13).

A showing of unexpected results must be factual. *In re Geisler*, 116 F.3d. at 1470. Therefore, we turn to the data provided in the Specification.

Example 1 compared conventional dried pet foods to pet food 1 containing 2% by weight of chicory and pet food 2 with 2% chicory and 2% by weight of linoleic acid, a long chain-fatty acid (Spec. 7). It is stated in the Specification that food 1 containing the chicory, and food 2 containing the chicory and linoleic acid, produce increased coat shininess, coat softness, skin hydration, and skin elasticity (Spec. 8).

Example 2 performed a similar comparison as in Example 1, but used foods with chicory and the long-chain fatty acids 1) alpha-linoleic acid (food 3); 2) eicosapentanoic acid and docosahexanoic acid (food 4); or 3) gamma-linoleic acid (food 5) (*id.* at 8-9). As with Example 1, the foods, when fed to pets, are stated to result in increased coat shininess, coat softness, skin hydration, and skin elasticity (*id.*).

This evidence is not adequate to rebut the Examiner’s *prima facie* case. Shields describes a pet food with chicory root and a long-chain fatty acid (FF2-5), the same components present in food 2 of Example 1. Long-chain fatty acids, added to the foods in Example 2 of the Specification, are explicitly taught by Shields as advantageous in maintaining healthy skin and coat (FF3). Marsh (FF12-13) and Matsuura (FF16, 17, & 21) also taught these benefits. Therefore, the improved results reported in the Specification with the long-chain fatty acids would have been expected by a person of

ordinary skill in the art. Appellants have not explained on what basis the results would have been unexpected to the ordinary skilled worker in the art.

The Specification also shows that a pet food with only chicory improved pet coat and hair as compared to a food without it (Spec. 7; food 1 of Example 1). The only prebiotic tested was chicory and it was tested at only one concentration of 2%. However, claim 1 is not limited to the type of prebiotic, and covers a broader range of concentrations from 0.1% to 20%. Appellants have not provided evidence that other prebiotics at concentrations as low as 0.1% would achieve the same results reported for 2% chicory when fed to pets. The results are therefore not commensurate with the full scope of the claimed subject matter. Appellants also did not establish that the base dried pet food used in Example 1 lacked long-chain fatty acids.

Recognition of benefit

It is well-established that an old process is not made patentable by merely recognizing something that was not known before. In this case, there is no difference in the steps carried out by Shields or Cavadini and those recited in claim 1. Thus, even if the prior art had not recognized the benefit of pre- and probiotics on skin and hair condition, such recognition is insufficient to render a claim to it patentable because both Shields and Cavadini had taught feeding a food to a pet with such components (FF3-5, 8-10).

Moreover, Matsuura – relied upon in the second obviousness rejection in combination with Shields and Cavadini – taught a food comprising

prebiotic (FF20), probiotic (FF18-19), and long chain fatty acids (FF17) for treating dermatosis (FF16), a skin condition. Therefore, Matsuura describes the same benefit recited in claim 1 and the same food components listed in claim 1 to achieve the benefit. Marsh also recognized a benefit of a long-chain fatty to promote healthy skin and coat (FF12-13).

CONCLUSIONS OF LAW & SUMMARY

The Examiner did not err in finding that Shields disclosed a prebiotic concentration that met the limitations of claim 1.

Appellants did not provide adequate evidence of unexpected results to rebut the Examiner's *prima facie* case of obviousness.

It was not necessary for the prior art to have recognized the benefit of prebiotics and probiotics on the skin and coat for the cited combination of prior art to have met all the limitations of claim 1.

The obviousness rejections of claim 1 are affirmed. Claims 4, 6, 8, 10, 12, 13, 15-17, 19-24, and 33-33 fall with claim 1 because separate arguments for their patentability were not provided. 37 C.F.R. 41.37(c)(1)(vii).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Appeal 2009-006346
Application 10/070,799

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